STATISTICAL ANALYSIS PLAN

Protocol Number: Pelle-926-202

Study Title: Double-Blind, Dose Escalating, Randomized, Vehicle-Controlled Proof of Concept Clinical Trial of Patidegib Gel 2%, 4%, and Vehicle Applied Once or Twice Daily to Decrease the GLI Biomarker in Sporadic Nodular Basal Cell Carcinomas

Development Phase of Study: 2A

Sponsor: PellePharm, Inc.
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PellePharm, Inc.

Revisions to the Statistical Analysis Plan described herein must be approved through a formal written amendment with the exception of minor editorial changes to tables, figures, or listing shells, and any necessary textual clarifications for programmers that do not affect the stated analysis variables, study endpoints, or statistical methods.

Change History:

Version	Date	Summary of Changes	Author
1.0	28Sep2017	Version 1.0	PPD

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1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	adverse event
ALT	Alanine aminotransferase
ANCOVA	analysis of covariance
AST	Aspartate aminotransferase
ATC	anatomical therapeutic chemical
BCC	Basal cell carcinoma
BCNS	basal cell nevus syndrome
BUN	blood urea nitrogen
cm	centimeters
CMH	Cochran-Mantel-Haenszel
CRF	case report form
eCRF	electronic case report form
ET	early termination
F	Fahrenheit
FDA	Food and Drug Administration
GLI 1	glioma-associated oncogene homolog 1
HH	hedgehog
HR	heart rate
hr(s)	hour(s)
ISGTA	Investigator Static Global Tumor Assessment
ITT	intent-to-treat
kg	kilograms
LOCF	last observation carried forward
max	maximum
MCH	Mean corpuscular hemoglobin
MCHC	Mean corpuscular hemoglobin concentration
MCV	Mean corpuscular volume
MedDRA	Medical Dictionary for Regulatory Activities
mg	milligram
min	minimum
mRNA	messenger ribonucleic acid
n	number of observations
N	number of subjects (sample size)

PSCP	primary skin care physician
QST	QST Consultations, Ltd.
RBC	Red Blood Cell
SAE	serious adverse event
SAS®	Statistical Analysis System (SAS® Institute Inc., Cary, NC)
SD	standard deviation
SEB	surgically eligible basal cell carcinoma
SMO	smoothened
SPF	skin protection factor
SOC	system organ class
TEAE	treatment-emergent adverse event
US	United States
UV	ultraviolet
WBC	White blood cell count
WHO	World Health Organization
WHO-DDE	World Health Organization Drug Dictionary

2. INTRODUCTION

PellePharm, Inc. is developing patidegib gel for the management of the burden of disease in patients with basal cell nevus syndrome (BCNS), a rare genetic disease characterized by the development of numerous basal cell carcinomas over a lifetime. This trial will evaluate the ability of patidegib gel to shrink BCC tumors in patients with sporadic BCCs as a proof-of-concept for the mechanism of patidegib on BCCs. It is hoped that results from this study will inform the dose and dosing regimen prior for future trials, thereby maximizing the therapeutic potential.

Patidegib is a semi-synthetic small molecule, and the topical drug product is manufactured with generally accepted, safe excipients. Oral patidegib has a good therapeutic efficacy versus locally advanced and metastatic BCCs but produces the same types of adverse effects as do other systemic HH inhibitors. Topical patidegib has been shown to be stable in the developed gel formulation and can be applied to mini-pig skin without irritation. Topical application of patidegib significantly reduces murine BCC tumor size in vivo and reduces GLI1 biomarker expression in vitro in human BCC tumor explants.

If proven to be safe and effective in future clinical trials patidegib gel may offer BCNS patients a safe and effective therapy to manage their burden of disease by decreasing the number of

surgeries they will require over their lifetime. This trial will evaluate the safety, the tolerability, and the ability of four different dosing regimens applied for 3 months to reduce the Hedgehog signaling pathway in nodular BCC tumors in patients with sporadic BCCs.

The goal of the present trial is to evaluate topical patidegib's safety, tolerability, and effects on the size of preexisting sporadic previously untreated nodular BCCs and thereby to establish a dose and dosing regimen for future trials in the BCNS orphan population. It is anticipated that subsequent trials will focus on reducing the number of facial surgeries required by patients with BCNS and not on the "treatment" of individual sporadic BCCs. If the efficacy with topical patidegib can approach the level of efficacy of oral HH inhibitors seen in BCNS patients while avoiding their systemic side effects, it would represent a major advance for BCNS patients.

3. STUDY OBJECTIVES

The primary objectives of the study are to evaluate the following:

1. The safety and tolerability of treatment with patidegib gel 2% or 4% or vehicle applied once or twice daily for 12 weeks.
2. The molecular efficacy of treatment as defined by reduction in the hedgehog (HH) signaling pathway after treatment with patidegib gel 2% or 4% or vehicle applied twice daily for 12 weeks to treatment-targeted BCCs.

The secondary objective of the study is to evaluate the following:

1. The clinical efficacy of patidegib as defined by the percent decrease in greatest diameter of baseline treatment targeted basal cell carcinomas after 12 weeks of treatment. Treatment targeted BCCs will be biopsied prior to treatment to confirm the clinical diagnosis of nodular BCC. Eligible tumors will have the clinical features of nodular BCC and prior to biopsy will be no less than 5 mm or greater than 20 mm in longest diameter on the face (excluding the nose and periorbital skin) and no less than 9 mm or greater than 20 mm in longest diameter at sites other than the face.

Exploratory objectives:

1. To evaluate the utility of an investigator static global tumor assessment (ISGTA) in assessing the proportion of baseline treatment-targeted BCCs that are evaluated as being clear or almost clear.
2. To evaluate the utility of blinded assessment of change in BCC size using photographs.

4. STUDY DESIGN

4.1 Overall Study Design

This is a double-blind, dose escalating, randomized, vehicle-controlled study designed to assess the efficacy and safety of patidegib gel 2% and 4% in comparison with vehicle applied once or twice daily. The population of subjects will be enrolled from the PPD .

Approximately 36 subjects who meet the study entry criteria will be randomized to one of four sequential cohorts. Each cohort will have 6 subjects randomized to active drug and 3 randomized to vehicle. The four sequential cohorts will be:

- Cohort 1: patidegib gel 2% or vehicle applied once daily,
- Cohort 2: patidegib gel 4% or vehicle applied once daily,
- Cohort 3: patidegib gel 2% or vehicle applied twice daily, and
- Cohort 4: patidegib gel 4% or vehicle applied twice daily.

As soon as one cohort has been enrolled the next cohort will be recruited. The study drug will be applied topically to the treatment-targeted nodular BCCs once or twice daily for 12 weeks of treatment.

Upon completion of the 12-week treatment period, all subjects will be asked to return to the investigational center for final evaluation. At the Week 12 visit the treatment site(s) will be excised. The area excised should at a minimum include the original diameter of the tumor. This means that if the tumor has shrunk in size the entire original area of the BCC will be excised, not just the visually apparent residual tumor. During the study, subjects will be allowed to use moisturizers and emollients and sunscreen. The Investigator will assess the areas affected at each visit.

The treatment-targeted BCC(s) will be identified by the Investigator at the Baseline visit and will be circled in ink at Baseline, Weeks 6 and 12, and photographed, and measured at all study visits (Baseline, Weeks 2, 6, 8, 10, and 12).

Biomarkers: On each subject one or two baseline previously untreated nodular BCCs designated as a treatment-targeted tumor will be biopsied and at the end of 12 weeks of treatment the treatment site(s) will be excised. Both samples will be evaluated histologically and for determination of GLI1 mRNA levels.

Blood samples for complete blood count and serum chemistry and urine for urinalysis will be collected from subjects at Screening, Week 6, and Week 12.

Subjects who terminate study participation early will be asked to complete all Week 12 assessments, as appropriate, prior to commencement of any alternative therapy for BCC (if possible). Subjects who discontinue from the study during the treatment period will not be replaced.

If signs or symptoms develop in the treatment areas during the treatment period that restrict daily activities or make continued application of the study drug difficult due to discomfort, the Investigator may instruct the subject to interrupt use of the study drug temporarily and to resume application of the study drug once the signs/symptoms have subsided. The Investigator should try to minimize study drug interruptions; and if needed, make best efforts to limit a "drug holiday" to no more than 7 days. If the study drug interruption does exceed 4 consecutive days, the Investigator should consult with the Medical Monitor to determine a course of action. If the study drug is interrupted, discontinued, or a concomitant medication is used to treat a sign or symptom, an AE shall be recorded.

Subjects who discontinue participation in the study due to clinically significant laboratory abnormalities or AEs will be asked to complete all Week 12 evaluations. Any subject who has an AE during the treatment period will be monitored by the Investigator until resolution (return to normal or to the baseline state) or stabilization, as determined by the Investigator.

In addition, application of study drug may be delayed or halted at any time if ongoing safety data evaluations raise concern for subject safety. If the subject participation is suspended, all of the subject's safety data will be reviewed by the Medical Monitor in conjunction with the Investigator to determine course of action.

4.1.1 Schedule of Visits and Assessments

The schedule of assessments can be found in Section 5.1 of the protocol.

4.1.2 Method of Assigning Subjects to Treatment Groups

This is a double-blinded study, in which the identity of the study drug will be unknown to Investigator and subjects, as well as to all individuals closely associated with the study.

Subjects will be enrolled into 1 of the 4 sequential study drug groups of 9 subjects with 6 being randomized to active and 3 to vehicle within each group. The sequential groups will be patidegib or vehicle gel 2% applied once daily, patidegib or vehicle gel 4% applied once daily, patidegib or vehicle gel 2% applied twice daily, patidegib or vehicle gel 4% applied twice daily. Each screened subject will be assigned a unique 5-digit study subject number assigned by the investigational center, which will consist of the 2 digit investigational center number and the 3 digit chronological screening order number, starting with 001 (e.g., 01001, 01002). The study

drug kit will be assigned to subjects based on a randomization code, and kits will be dispensed to the subjects at Baseline in the order that they are enrolled by taking the lowest numbered kit available in inventory at the investigational site. A study drug accountability log will document the inventory and dispensing of study drug at the investigational center.

4.1.3 Blinding

The study drugs will be packaged and labeled identically, and the study drug kits will be numbered sequentially and dispensed randomly to the subjects on the study. Study drug supplies will be distributed to the investigational center to maintain the randomization ratio.

As a double-blinded study, the Investigators, the site staff, PellePharm, and the Clinical Monitor(s) will not be aware of the treatment assigned to the individual study subjects. Delegated staff members at the investigational center will dispense the study drugs and will collect and weigh all used and unused study drug tubes as scheduled.

The treatment assignments for all enrolled subjects will be completely unblinded only after the conclusion of the treatment phase of the study. However, after Cohorts 1 and 2 have complete biopsy results, and again after Cohort 3 has complete biopsy results, the sponsor and the CRO will be unblinded in order to assess limited safety and efficacy results.

5. EFFICACY AND SAFETY ENDPOINTS

5.1 Efficacy Endpoints

The efficacy endpoints are intended to compare once and twice daily application of 2% patidegib gel, 4% patidegib gel, and vehicle gel. Efficacy assessments will be summarized descriptively by treatment group and visit. P-values will be provided for descriptive purposes only.

5.1.1 Primary Efficacy Endpoint

The primary efficacy endpoint is change in GLI1 mRNA levels in drug-treated versus vehicle-treated tumors at Week 12.

5.1.2 Secondary Efficacy Endpoint

The secondary efficacy endpoint is the decrease in tumor size defined in two ways:

1. Percent of baseline treatment targeted BCCs with Complete or Partial Response at Week 12 as assessed by blinded photographic review[1] where Complete Response is determined when there is no longer any visible evidence of a lesion consistent with BCC at the site, Partial Response is determined when although a BCC still remains at this site, it has demonstrated a visible decrease in size compared with baseline, and No Response is

determined when the BCC has not demonstrated any visible decrease in size compared with baseline, and;

2. Percent decrease in the greatest diameter of baseline treatment targeted BCCs at Week 12.

5.1.3 Exploratory Efficacy Endpoints

The first exploratory endpoint is the proportion of baseline treatment-targeted BCCs that are evaluated as being clear or almost clear in the investigator static global tumor assessment (ISGTA) assessment.

The second exploratory endpoint is the proportion of baseline treated tumors that are smaller based on blinded photographic review. Tumor area will also be assessed at each study visit. From tumor area, a 'Yes/No' for whether the tumor is smaller will be derived such that if area at visit is less than area at baseline this is 'Yes'.

5.2 Safety Endpoints

Safety will be assessed through adverse events, dermal safety and tolerability, safety laboratory values and vital signs measurements, and pregnancy tests.

6. STATISTICAL AND ANALYTICAL PLANS

6.1 General Methodology

All statistical processing will be performed using Statistical Analysis System (SAS®) unless otherwise stated. No interim analyses are planned. If determined appropriate by the Sponsor, limited safety and efficacy interim analysis on tumor shrinkage and biomarkers may be performed.

Formal inferential testing will not be performed, however p-values will be provided for descriptive purposes. Descriptive statistics will be used to provide an overview of the efficacy and safety results. P-values which are supplied are for descriptive purposes only. For categorical parameters, the number and percentage of subjects in each category will be presented. For continuous parameters, descriptive statistics will include n (number of subjects), mean, standard deviation (SD), median, minimum (min), and maximum (max). For by treatment group summaries the vehicle gel group from each cohort will be combined into a single group.

The last observation carried forward method (LOCF) will be used to impute missing secondary and exploratory efficacy data (i.e., the last available on-therapy observation for a subject will be used to estimate subsequent missing data points). Analyses will also be carried out on an 'as

observed' basis without imputation. No imputations will be made for missing primary endpoint data or safety data.

6.1.1 Statistical Analysis

All analyses will be performed by QST using SAS® Version 9.3 or later. All summary tables and data listings will be prepared utilizing SAS® software.

The standard operating procedures (SOPs) of QST will be followed in the creation and quality control of all data displays and analyses.

6.1.2 Baseline Definition

Baseline is defined as the last non-missing assessment prior to first dose of study drug.

6.1.3 Visit Windowing

Data will be summarized based on nominal visit indications with the exception of data captured at early termination and unscheduled visits. Data from early termination and unscheduled visits will be summarized based on mapped visit values. The analysis windows for early termination and unscheduled visits are presented in the following table.

Analysis Windows for Efficacy and Safety Assessments

Scheduled Visit	Target Study Day	Window (Days)
Week 2	15	13 to 17
Week 6	43	40 to 46
Week 8	57	54 to 60
Week 10	71	68 to 74
Week 12	85	82 to 88
Week 14	99	92 to 106

Data collected at early termination and unscheduled visits prior to study day 13 will not be analyzed, with the exception of those identified as Baseline values. Data collected at early termination and unscheduled visits after study day 106 will not be included in analyses.

The definition for the study day included in each study window is defined as below:

Study Day Prior to Day 1 = Visit Date – Baseline Date

Study Day On or After Day 1 = Visit Date – Baseline Date + 1.

If an assessment's mapped visit is a visit at which the subject has data from a scheduled visit present, or if no analyses are planned for the assessment at the mapped visit, or if the data maps to a time period not covered by windowing, the data collected at the early termination or unscheduled visit will not be included in analyses.

In the event of multiple values from unscheduled or early termination assessments within an analysis window, the value closest to the scheduled visit target study day will be used for analyses (assuming there were no results from the scheduled visit present). If two values tie as closest to the time point (for example, one value is before and the other value is after the time point), then the later value will be selected.

Data collected at all visits will be included in the data listings with visit presented as reported by the site.

6.1.4 Adjustments for Covariates

Treatment group as factor and baseline values as covariate will be included in the primary and secondary endpoints analyses.

6.1.5 Handling of Dropouts or Missing Data

If a partial date is recorded for an adverse event start or end date, the following procedure will be followed. Other missing safety data dates will not be imputed.

If a partial date is reported where the day is missing, then the day will be imputed as the first day of the month unless the month is the same month as the first dose in which case the day will be that of first dose with the month and year remaining the same. If a partial date is reported where the month is missing, then the month will be imputed to January unless the year is the same year as the first dose in which case the month will be that of first dose with the year remaining the same. If a partial date where both the day and month is missing, follow details as stated previously.

Missing data post-Baseline through Week 12 will be imputed using last observation carried forward (LOCF) for the secondary endpoint of tumor size as assessed by the investigator. Specifically, if a single diameter is missing then that SEB's previous measurement will be carried forward. The analysis will also be performed without imputation of missing data. For the secondary endpoint of GLI1, no missing data will be imputed.

6.1.6 Interim Analyses and Data Monitoring

As stated in the protocol, if determined appropriate by the Sponsor, limited safety and efficacy interim analysis on tumor shrinkage and biomarkers may be performed.

Once biomarker results are available for subjects in Cohorts 1 and 2, and again after Cohort 3 subjects have biomarker results, the database will be used to report on limited safety and efficacy results. The sponsor and the CRO (QST) will be unblinded at this time. Site staff will remain blinded.

6.1.7 Multicenter Studies

The study will be conducted at one metasite in the United States with the intention of pooling the results for analysis.

6.1.8 Multiple Comparisons/Multiplicity

Not applicable. Inferential tests will not be performed.

6.1.9 Use of an Efficacy Subset of Subjects

A Per Protocol population is defined below.

6.1.10 Active-Control Studies Intended to Show Equivalence

Not applicable to this study.

6.1.11 Examination of Subgroups

Not applicable to this study.

6.2 Disposition of Subjects

The number of subjects included in each analysis population (ITT, Safety, and Per Protocol) will be summarized by treatment group. The number of subjects randomized, completed, and discontinued (including the reasons for discontinuation) will be summarized for each treatment group.

Reasons for exclusion from study populations will be included in a by-subject listing.

6.3 Protocol Deviations

All protocol deviations will be reported to PellePharm and recorded throughout the study. A listing of protocol deviations by treatment by subject will be included in the final study report.

6.4 Data Sets Analyzed

6.4.1 Intent-to-Treat (ITT) Population

All subjects who are randomized and dispensed study drug will be included in the ITT analysis set. Subjects will be analyzed according to the treatment group they were randomized. All efficacy analyses will be presented using the ITT population and the Per Protocol population.

6.4.2 Safety Population

All subjects who are randomized, receive at least 1 confirmed dose of study drug and have at least one post-baseline safety assessment will be included in the safety analysis set. All safety analyses will be according to the treatment actually received.

6.4.3 Per Protocol (PP) Population

All subjects in the ITT population who complete the Week 12 evaluation without any significant protocol violations will be included in the PP population and analyzed according to the treatment group they received. The PP population will include subjects in the safety population who do not meet any of the following criteria:

- Violated the inclusion/exclusion criteria;
- Have taken any interfering concomitant medication;
- Did not attend the Week 12 visit;
- Have not been compliant with the dosing regimen, between 80% to 120%
- Had samples with insufficient BCC
- Had tumors where the diameter was incorrectly measured based on review of photographs

Subjects that discontinue from the study due to an adverse event related to study treatment or documented lack of treatment effect will be included in the PP population. Prior to breaking the blind, other additional criteria may be added to the list to accommodate for unforeseen events that occurred during the conduct of the trial that result in noteworthy study protocol violations.

Efficacy analyses performed on a by-tumor basis will include tumors from subjects who are not excluded for any of the above reasons.

All efficacy analyses will be performed on the ITT population as well as on the PP population.

6.5 Demographic and Other Baseline Characteristics

All baseline summaries will be done on the ITT population.

Sex, race, and ethnicity will be summarized by counts and percentages. Age, height (cm), and weight (kg) will be summarized with descriptive statistics.

Medical histories will be coded using the MedDRA dictionary and presented in a by-subject listing.

6.6 Prior and Concomitant Medications

Concomitant therapies will be coded to preferred name and Anatomical Therapeutic Chemical (ATC) classification of ingredients using the World Health Organization (WHO) Drug dictionary (WHO-DDE).

A by-subject listing of all prior and concomitant medications will be presented. Medications that start prior to first dose but continue after the first dose will be considered a concomitant medication. Medications that are unable to be classified as either prior or concomitant due to missing data will not be considered a concomitant medication.

6.7 Analysis of Efficacy

All efficacy analysis will be done on both the ITT and PP populations.

6.7.1 Primary Efficacy Analysis

The primary endpoint of change in GLI1 mRNA levels will be evaluated with an analysis of covariance (ANCOVA) with treatment group as factor and baseline value as covariate. Analysis is on a by tumor level. Pairwise comparisons as well as any treated (combining all patidegib groups) versus vehicle will be performed using contrasts within the ANCOVA.

Additionally, if number of results is sufficient, a t-test will be done to perform pairwise comparisons of change in GLI1 mRNA levels of each treatment group with vehicle (and combined patidegib versus vehicle). If assumptions required for a t-test are not met, then a Mann Whitney U test will be performed.

Data will be summarized by visit. Both change from baseline and percent change from baseline will be presented.

This analysis will be done for 2 regions (1) BCC and (2) BCC + tumor-associated stroma.

No imputation on GLI1 data will be performed.

6.7.2 Secondary Efficacy Analysis

The first secondary endpoint, the proportion of treatment targeted BCCs with Complete or Partial Response as determined by blinded photographic review will be evaluated using a 2-sided Fisher's Exact test. This analysis will be performed on all available data with no imputation of missing data. Both pairwise comparisons between treatment groups and all treated (combining all patidegib groups) versus vehicle will be done.

The second secondary endpoint, the greatest diameter of all treatment targeted BCCs, will be evaluated similarly to the primary endpoint.This analysis will be performed using LOCF imputation as well as 'as observed' (i.e. no imputation of missing data).

6.7.3 Exploratory Efficacy Analysis

The exploratory endpoint of investigator static global tumor assessment (ISGTA) will be summarized by visit on a by tumor level. Proportion with success as defined by Clear/Almost Clear will be provided. Results will be analyzed with a Cochran-Mantel-Haenszel (CMH) test.

Tumor area will be evaluated with an analysis of covariance (ANCOVA) with treatment group as factor and baseline value as covariate. Analysis is on a by tumor level. Pairwise comparisons as well as any treated (combining all patidegib groups) versus vehicle will be performed using contrasts within the ANCOVA.

The proportion of baseline treated tumors are smaller at each study visit based on photographic review will be summarized by treatment group. Results will be analyzed between groups and all treated (combining all patidegib groups) versus vehicle with a CMH test. Tumor area will be summarized by visit.

6.8 Safety Evaluation

6.8.1 Extent of Exposure and Compliance

The extent of exposure to study drug in each treatment group will be summarized by days with applications, total number of applications, and number of missed applications. This data will also be provided in a listing.

Percent compliance will be calculated for each subject as follows:

(a) Expected Number of Applications = (Date of Last Application – Date of First Application + 1) * Number of Expected Applications per day, accounting for possible single applications on First and/or Last Day

(b) Total Number of Applications = Expected Number of Applications – Total Number of Missed Applications

Compliance = (b) / (a) * 100

6.8.2 Adverse Events

All AEs that occur during the study will be recorded and classified on the basis of Medical Dictionary for Regulatory Activities (MedDRA) terminology. Treatment-emergent Aes (TEAEs) are defined as Aes with an onset on or after the date of the first study drug application. Adverse events noted prior to the first study drug administration that worsen after Baseline will also be reported as Aes and included in the summaries.

Treatment-emergent Aes will be summarized by treatment group, the number of subjects reporting a TEAE, SOC, preferred term, severity, relationship to study drug (causality), and seriousness. When summarizing Aes by severity and relationship, each subject will be counted once within a system organ class or a preferred term by using the event with the highest severity and greatest relationship within each classification.

If relationship to study drug is reported as unknown, possible, probable or definite, then this is defined as related. If relationship to study drug is reported as unlikely or not related, then this is defined as unrelated.

Serious Aes will be summarized by treatment group, severity and relationship to study drug.

Listings will be presented for all adverse events as well as for serious adverse events and adverse events leading to study drug withdrawal.

6.8.3 Clinical Laboratory Evaluation

Laboratory test results will be summarized with descriptive statistics at Baseline and Week 12. Additionally, shifts from Baseline to Week 12 in laboratory test results based on normal ranges will be summarized with frequency counts and percentages. Individual laboratory test results will be presented in a by-subject listing.

6.8.4 Other Observations Related to Safety

6.8.4.1 Dermal Safety and Tolerability

The frequency of dermal safety and tolerability assessments including pain/burning, pruritus, erythema, edema, and scabbing/crusting will be summarized by treatment group and visit. All dermal safety and tolerability results will be listed.

6.8.4.2 Systemic Symptoms

Systemic symptoms will be summarized by treatment group and visit. Additionally, results will be listed.

6.8.4.3 Vital Signs

Vital signs will be summarized with descriptive statistics at Baseline and each applicable study visit. Changes from Baseline in vital signs will also be summarized.

Vital sign measurements will be listed.

6.8.4.4 Physical Examination

Physical examination data will be presented in a by-subject listing.

7. DETERMINATION OF SAMPLE SIZE

This is a dose ranging study.

8. CHANGES IN THE PLANNED ANALYSES

The protocol defines the secondary objective as the clinical efficacy of patidegib as defined by the percent decrease in greatest diameter of baseline treatment targeted basal cell carcinomas after 12 weeks of treatment. The secondary objective will now also include the clinical efficacy of patidegib as defined by the proportion of Complete or Partial Response in treatment targeted BCCs after 12 weeks of treatment as defined by blinded photographic review.References

9. REFERENCES

1. Skvara H, Kalthoff F, Meingassner JG, Wolff-Winiski B, Aschauer H, Kelleher JF, Wu X, Pan S, Mickel L, Schuster C, Stary G, Jalili A, David OJ, Emotte C, Antunes AMC, Rose K, Decker J, Carlson I, Gardner H, Stuetz A, Bertolino AP, Stingl G, De Rie MA. Topical Treatment of Basal Cell Carcinomas in Nevoid Basal Cell Carcinoma Syndrome with a Smoothened Inhibitor., J Invest Dermatology 2011.

10. INDEX OF PLANNED END-OF-TEXT TABLES AND FIGURES

Table 14.1.1: Summary of Subject Disposition
(All Subjects)

	Patidegib Gel 2% QD	Patidegib Gel 2% BID	Patidegib Gel 4% QD	Patidegib Gel 4% BID	Vehicle Gel
Number of Subjects Randomized	xx	xx	xx	xx	xx
Number of Subjects Included in the ITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the ITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the Per Protocol Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the Per Protocol Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Completed Study					
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation					
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-Up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lack of Efficacy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Violation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Disease Progression	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.1: Summary of Subject Demographics and Baseline Characteristics
(Intent-to-Treat Population)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Age (years)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Sex					
n	xx	xx	xx	xx	xx
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity					
n	xx	xx	xx	xx	xx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race					
n	xx	xx	xx	xx	xx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Multiple/Other[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing xx for a complete list of all other races.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.1: Summary of Subject Demographics and Baseline Characteristics
(Intent-to-Treat Population)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Height (cm)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Weight (kg)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

[a] See Listing xx for a complete list of all other races.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1: Analysis of the Primary Efficacy Endpoint: Percent Change in GLI1 mRNA Levels at Week 12
(Intent-to-Treat Population)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
1: BCC region H-Score					
Baseline					
Number of tumors	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12					
Number of tumors	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline[a]					
Number of tumors	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline[a]					
Number of tumors	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
At least 40% Decrease from Baseline	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

P-value versus Vehicle Gel[b]	x.xxx	x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% QD[b]		x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% BID[b]			x.xxx	x.xxx	
P-value versus Patidegib Gel 4% QD[b]				x.xxx	
P-value All Patidegib vs Vehicle Gel					x.xxx
P-value versus Vehicle Gel[c]	x.xxx	x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% QD[c]		x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% BID[c]			x.xxx	x.xxx	
P-value versus Patidegib Gel 4% QD[c]				x.xxx	
P-value All Patidegib vs Vehicle Gel					x.xxx

Repeat Above for 1:BCC + tumor-associated stroma region H-Score

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[a] Change from Baseline calculated as (Week 12 – Baseline). Percent Change from Baseline calculated as (Week 12 - Baseline) / Baseline * 100.
[b] P-value of pairwise comparison using ANCOVA with a factor of treatment group and using Baseline value as a covariate.
[c] P-value of pairwise comparison using t-test *(or Mann Whitney U if the case)*.
Note: Missing values are not imputed; all available data is summarized.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.2: Analysis of the Primary Efficacy Endpoint: Percent Change in GLI1 mRNA Levels at Week 12 (Per Protocol Population)

As above Table 14.2.1.1 but for the Per Protocol Population

Table 14.2.2.1.1: Analysis of the Secondary Efficacy Endpoint: Proportion of CR/PR Response at Week 12
(Intent-to-Treat Population)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Proportion of CR/PR Response at Week 12[a]					
Number of tumors	xx	xx	xx	xx	xx
CR / PR	xx.x	xx.x	xx.x	xx.x	xx.x
Non Response	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
P-value versus Vehicle Gel[c]	x.xxx	x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% QD[c]		x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% BID[c]			x.xxx	x.xxx	
P-value versus Patidegib Gel 4% QD[c]				x.xxx	
P-value All Patidegib vs Vehicle Gel					x.xxx

[a] As assessed by blinded photographic review.
[b] P-value of pairwise comparison using 2-sided Fisher's Exact test.
Note: Missing values are not imputed.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.2: Analysis of the Secondary Efficacy Endpoint: Proportion of CR/PR Response at Week 12 (Per Protocol Population)

Table 14.2.2.2.1: Analysis of the Secondary Efficacy Endpoint: Percent Decrease in Baseline Treatment Targeted Tumor Size at Week 12 (LOCF)
(Intent-to-Treat Population)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Percent Decrease in Greatest Diameter of Treatment Targeted BCCs at Week 12[a]					
Number of tumors	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
P-value versus Vehicle Gel[b]	x.xxx	x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% QD[b]		x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% BID[b]			x.xxx	x.xxx	
P-value versus Patidegib Gel 4% QD[b]				x.xxx	
P-value All Patidegib vs Vehicle Gel					x.xxx
P-value versus Vehicle Gel[c]	x.xxx	x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% QD[c]		x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% BID[c]			x.xxx	x.xxx	
P-value versus Patidegib Gel 4% QD[c]				x.xxx	
P-value All Patidegib vs Vehicle Gel					x.xxx

[a] Percent decrease calculated as (Baseline - Week 12) / Baseline * 100.
[b] P-value of pairwise comparison using ANCOVA with treatment group as a factor and Baseline value as a covariate.
[c] P-value of pairwise comparison using t-test *(or Mann Whitney U if the case)*.
Note: Missing values are imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.2.2: Analysis of the Secondary Efficacy Endpoint: Percent Decrease in Baseline Treatment Targeted Tumor Size at Week 12 (LOCF)
(Per Protocol Population)

As above Table 14.2.2.1 but for Per Protocol population.

Table 14.2.2.2.3: Analysis of the Secondary Efficacy Endpoint: Percent Decrease in Baseline Treatment Targeted Tumor Size at Week 12 (As Observed)
(Intent-to-Treat Population)

As above Table 14.2.2.1 but with no imputation and the following Note: Missing values are not imputed.

Table 14.2.2.2.4: Analysis of the Secondary Efficacy Endpoint: Percent Decrease in Baseline Treatment Targeted Tumor Size at Week 12 (As Observed)
(Per Protocol Population)

As above Table 14.2.2.2 but for Per Protocol population.

Table 14.2.2.2.5: Summary of Baseline Treatment Targeted Tumor Size at Weeks 2, 6, 8 and 10 (LOCF)
(Intent-to-Treat Population)
(Page 1 of x)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Baseline					
Number of tumors	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 2					
Number of tumors	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline[a]					
Number of tumors	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Continue for Weeks 6, 8 and 10

[a] Percent change calculated as (Follow-up - Baseline) / Baseline * 100.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.2.6: Summary of Baseline Treatment Targeted Tumor Size at Weeks 2, 6, 8 and 10 (LOCF)
(Per Protocol Population)

As Table 14.2.2.5 but Per Protocol.

Table 14.2.2.2.7: Summary of Baseline Treatment Targeted Tumor Size at Weeks 2, 6, 8 and 10 (as Observed)
(Intent-to-Treat Population)

As above Table 14.2.2.5 but with no imputation. Replace Note with Note: Missing values are not imputed.

Table 14.2.2.2.8: Summary of Baseline Treatment Targeted Tumor Size at Weeks 2, 6, 8 and 10 (as Observed)
(Per Protocol Population)

As Table 14.2.2.7 but Per Protocol.

Table 14.2.3.1: Analysis of the Exploratory Efficacy Endpoint: ISGTA at Weeks 2, 6, 8, 10 and 12
(Intent-to-Treat Population)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Baseline					
Number of tumors	xx	xx	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Minimal residual tumor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Clearly visible tumor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2					
Number of tumors	xx	xx	xx	xx	xx
0 – Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Almost clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Minimal residual tumor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Clearly visible tumor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Treatment Success[a]	xx	xx	xx	xx	xx
Success	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value versus Vehicle Gel[b]	x.xxx	x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% QD[b]		x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% BID[b]			x.xxx	x.xxx	
P-value versus Patidegib Gel 4% QD[b]				x.xxx	

Repeat for Weeks 6, 8 ,10 ,12

[a] Success is defined as Clear or Almost clear.
[b] P-value from Cochran-Mantel-Haenszel (CMH) test.
Note: Missing values imputed using LOCF.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.2: Analysis of the Exploratory Efficacy Endpoint: ISGTA at Weeks 2, 6, 8, 10 and 12
(Per Protocol Population)

As Table 14.2.3.1 for Per Protocol

Table 14.2.4.1: Analysis of the Exploratory Efficacy Endpoint: Area of Baseline Treated Tumors based on Photographic Review
(Intent-to-Treat Population)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Baseline					
Number of tumors	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Mid-Study					
Number of tumors	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Percent Change from Baseline[a]					
Number of tumors	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Smaller	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not smaller	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
P-value versus Vehicle Gel[b]	x.xxx	x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% QD[b]		x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% BID[b]			x.xxx	x.xxx	
P-value versus Patidegib Gel 4% QD[b]				x.xxx	
P-value All Patidegib vs Vehicle Gel[b]					x.xxx

P-value versus Vehicle Gel[c]	x.xxx	x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% QD[c]		x.xxx	x.xxx	x.xxx	
P-value versus Patidegib Gel 2% BID[c]			x.xxx	x.xxx	
P-value versus Patidegib Gel 4% QD[c]				x.xxx	
P-value All Patidegib vs Vehicle Gel[c]					x.xxx

Repeat for Week 12.

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[a] Defined as demonstrating no residual BCC.
[b] P-value of pairwise comparison using ANCOVA with treatment group as a factor and Baseline value as a covariate.
[c] P-value from Cochran-Mantel-Haenszel (CMH) test.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.2: Analysis of the Exploratory Efficacy Endpoint: Area of Baseline Treated Tumors based on Photographic Review (Per Protocol Population)
As Table 14.2.4.1 but using Per Protocol population.

Table 14.3.1.1: Summary of Extent of Exposure and Compliance
(Safety Population)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Number of Days oaf Exposure					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Number of Applications[a]					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Number of Missed Applications					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Compliance (%)					
N	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

[a] The total number of applications was calculated form the first date of treatment and the last date of treatment minus the missed applications.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.4.4: Analysis of the Exploratory Efficacy Endpoint: Area of Baseline Treated Tumors based on Photographic Review (Per Protocol Population)

Table 14.3.1.2.1: Summary of Dermal Safety and Tolerability
(Safety Population)
(Page 1 of x)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Pain / Burning					
Baseline					
Number of tumors	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2					
Number of tumors	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Continue for Weeks 6, 8, 10, 12

Repeat for Pruritus, Erythema, Edema, Scabbing / Crusting

Note: Local safety and tolerability is reported by the subject as the greatest intensity since the last visit or within 24 hours at Baseline.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2.2: Summary of Systemic Symptoms
(Safety Population)
(Page 1 of x)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Fatigue					
Baseline					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Continue for Weeks 8, 10, 12

Repeat for Loss or Change in Taste, Nausea, Vomiting, Diarrhea, Muscle Spasms or Cramps, Changes of Quality or Quantity of Hair in Treated Areas, Change in Frequency of Shaving, Other Systemic Sign or Symptoms, Other

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.1.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)
(Page 1 of 2)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Number (%) of Subjects Reporting At Least One Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Discontinued Study Medication due to Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Maximum Severity					
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongest Relationship to Study Medication					
Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after use of study medication. Not Related includes Not Related and Unlikely. Related includes Possible, Probable or Definite. Any unknown relationship is defined as Related. A subject is counted once according to maximum severity and relationship.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.1.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Maximum Severity within Relationship to Study Medication					
Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset after use of study medication. Not Related includes Not Related and Unlikely. Related includes Possible, Probable or Definite. Any unknown relationship is defined as Related. A subject is counted once according to maximum severity and relationship.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.1.2: Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA dictionary (Version 19.0). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: Treatment-emergent adverse events are those with an onset after use of study medication.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.1.3: Summary of Treatment-Emergent Adverse Events by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity	Patidegib Gel 2% QD N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
System Organ Class	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA dictionary (Version 19.0). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.

Note: Treatment-emergent adverse events are those with an onset after use of study medication.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.1.4: Summary of Treatment-Emergent Adverse Events by Relationship
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
System Organ Class	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Unrelated	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA dictionary (Version 19.0). At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the strongest reported relationship.

Note: Treatment-emergent adverse events are those with an onset after use of study medication. Not Related includes Not Related and Unlikely, Related includes Possible, Probable, or Definite.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.2.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics (Safety Population)

Similar to Table 14.3.2.1.1.

Table 14.3.2.2.2: Summary of Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term (Safety Population)

Similar to Table 14.3.2.1.2.

Table 14.3.2.2.3: Summary of Treatment-Emergent Serious Adverse Events by Severity (Safety Population)

Similar to Table 14.3.2.1.3.

Table 14.3.2.2.4: Summary of Treatment-Emergent Serious Adverse Events by Relationship (Safety Population)

Similar to Table 14.3.2.1.4.

Table 14.3.3.1: Summary of Chemistry Laboratory Results
(Safety Population)
(Page 1 of xx)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Alanine Aminotransferase (U/L)					
Baseline					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 6					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline[a]					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Continue for Week 12
Repeat for all Chemistry

[a] Baseline is the last non-missing assessment prior to the first dose of study drug.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.2: Summary of Hematology Laboratory Results (Safety Population)

Similar to Table 14.3.3.1.

Table 14.3.3.3: Summary of Quantitative Urinalysis Laboratory Results (Safety Population)

Similar to Table 14.3.3.1.

Table 14.3.3.4: Summary of Categorical Urinalysis Laboratory Results
(Safety Population)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Bacteria (/HPF)					
Baseline[a]					
N	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
NONE SEEN	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 6					
N	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
NONE SEEN	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12					
N	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
NONE SEEN	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Repeat for other qualitative urinalysis.					

[a] Baseline is the last non-missing assessment prior to the first dose of study drug.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.5: Summary of Chemistry Laboratory Results - Shift Table
(Safety Population)
(Page 1 of x)

		Week 6								
		Patidegib Gel 2% QD (N=xx)			Patidegib Gel 2% BID (N=xx)			Patidegib Gel 4% QD (N=xx)		
	Baseline	**BNL**	**WNL**	**ANL**	**BNL**	**WNL**	**ANL**	**BNL**	**WNL**	**ANL**
Test name (units)	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

		Patidegib Gel 4% BID (N=xx)			Vehicle Gel (N=xx)		
	Baseline	**BNL**	**WNL**	**ANL**	**BNL**	**WNL**	**ANL**
	BNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	WNL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	ANL	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[continue for all tests]

Continue for Week 12

Note: BNL=Below Normal Limit, WNL=Within Normal Limit, ANL=Above Normal Limit.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.6: Summary of Hematology Laboratory Results - Shift Table (Safety Population)

Similar to Table 14.3.3.5.

Table 14.3.3.7: Summary of Quantitative Urinalysis Laboratory Results - Shift Table (Safety Population)

Similar to Table 14.3.3.5.

Table 14.3.4.1: Summary of Vital Signs
(Safety Population)
(Page 1 of xx)

	Patidegib Gel 2% QD (N=xx)	Patidegib Gel 2% BID (N=xx)	Patidegib Gel 4% QD (N=xx)	Patidegib Gel 4% BID (N=xx)	Vehicle Gel (N=xx)
Diastolic Blood Pressure (mmHg)					
Baseline					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Week 12					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx
Change from Baseline					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	xx to xx

Continue for all vital signs in order as in CRF: Systolic BP, Diastolic BP, Heart Rate, Resp Rate, Oral Temp, (height and weight) .

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

11. INDEX OF PLANNED LISTINGS

Listing 16.1.7: Randomization Scheme
(Page xx of yy)

Subject	Age/Sex	Eval	Randomization Date	Date of First Application of Study Drug	Assigned Arm	Actual Arm
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx	xxxxxx	xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx	xxxxxx	xxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxx	xxxxxx	xxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.1.1: End of Study Information
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Date of First Application of Study Drug	Date of Last Application of Study Drug	Date of Study Completion/ Discontinuation (Day)[1]	Did Subject Complete the Study	Primary Reason for Study Discontinuation
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xx	xxxxx x xxxxxxx xxxxxx xxx xx xxxx xxxxxxxxx xxxxx xxxx xxxxx xxx xxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xx	xxxxx x xxxxxxx xxxxxx xxx xx xxxx xxxxxxxxx xxxxx xxxx xxxxx xxx xxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx	

[1] Day is calculated as date - Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date - Date of first dose + 1 for dates on or after Baseline.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Note to Programmer: The 'If Adverse Event, Protocol Violation, or Other, Please Specify' free text box should all be concatenated with Primary Reason for Study Discontinuation

Listing 16.2.1.2: Discontinued Subjects
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Date of First Application of Study Drug	Date of Last Application of Study Drug	Date of Discontinuation (Day)[1]	Primary Reason for Study Discontinuation
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxxxx x xxxxxxx xxxxxx xxx xx xxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxxxx x xxxxxxx xxxxxx xxx xx xxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xx xxxxx x xxxxxxx xxxxxx xxx xx xxxx xxxxxxxxx xxxxx xxxx xxxxx xxx xxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx xxxx	xxx

[1] Day is calculated as date - Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date - Date of first dose + 1 for dates on or after Baseline.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Note to Programmer: The 'If Adverse Event, Protocol Violation, or Other, Please Specify' free text box should all be concatenated with Primary Reason for Study Discontinuation

Listing 16.2.1.3: Screen Failures
(Page xx of yy)

Subject	Age/Sex	Reason for Exclusion
xxxxxx	xxxx	xxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Note to Programmer: If Inclusion Criteria Not Met or Exclusion Criteria Met, then include which, eg. Inclusion Criteria Not Met: Inclusion Criteria 5

Listing 16.2.2: Inclusion/Exclusion Criteria Violations
(Page xx of yy)

Subject	Age/Sex	Eval	Criteria Failed	Description
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.3: Analysis Populations
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Population	Included	Reason(s) Excluded
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	
		Per Protocol	xxx	
xxxxxx	xxxx	Intent-to-Treat	xxx	
		Safety	xxx	
		Per Protocol	xxx	

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.4.1: Subject Demographic Information
Treatment Arm
(Page xx of yy)

Subject	Eval	Date of Birth	A: Age S: Sex	R: Race E: Ethnicity	Informed Consent Date
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxxx xxxxxxxx xx xxxxx xxxxxxx xxxxxxxx xxxxxxxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.4.2.1: Unique Medical History Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Medical History Verbatim Term
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx
xxxx xxx xxxxx	xxxx xxx xxxxx	xxxx
		xxxxxx xxxxxxxxxx xx xxxxxx
		xxxxxx xxxxxxxxxx xx xxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 19.0).

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by System Organ Class, Preferred Term, and Verbatim Term.

Listing 16.2.4.2.2: Medical History
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	NBCC Dx Date	Any unresolved or clinically relevant conditions?	Condition/Surgery Verbatim Term	P: MedDRA Preferred Term S: MedDRA System Organ Class	S: Onset/Surgery Date O: Ongoing
xxxxxx	xxxx	xxxxxxxx	xxxxxx	xx	xxxxxxxxxxxxxxxxxxxx	P: xxxx xxx xxxxx S: xxxx xxx xxxxx	S: xxxxxxx O: xxxxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 19.0).

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject Number, Verbatim Term, Start Date, and End Date. Medical History term of Nodular Basal Cell Carcinoma should also be included.

Listing 16.2.4.3: Abbreviated Physical Examination
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date	Was Physical Examination Performed?
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx
			xxxx xx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx
			xxxx xxxxxxxx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx
			xxxx xx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx
			xxxx xxxxxxxx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx
			xxxx xx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx
			xxxx xxxxxxxx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx
			xxxx xx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx
			xxxx xxxxxxxx	xxxxxxxxxx	xxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.4.4.1: Unique Medication Names Coded to WHO-DDE ATC Level 2 Terms and Preferred Names
(Page xx of yy)

ATC Level 2 Term	Standardized Medication Name	Medication Name	I: Indication R: Route
xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
		xxxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
		xxxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx

Note: Standardized Medication Name and ATC Level 2 Term map to the WHO-DDE (Version March 1, 2016).

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by ATC Level 2 Term, Standardized Medication Name, Medication Name, Indication, and Route.

Listing 16.2.4.4.2: Prior and Concomitant Medications
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	M: Medication Name P: Standardized Medication Name A: ATC Level 2 Term I: Indication T: Taken for Adverse Event	F: Date of First Application S: Medication Start Date (Day)[1] E: Medication End Date (Day)[1] O: Ongoing	D: Dose U: Unit F: Frequency R: Route
xxxxxx	xxxx	xxxxxxxx	M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx I: xxxxxx xxxxxxxx T: xxxxxxxx	F: xxxxxxxxxxxxx S: xxxxxxxxxx E: xxxxxxxxxx O: xxxxxxx	D: xx U: xx F: xxxx R:xxxx
			M: xxxxxxxxxxxxx P: xxxxxxxxxxxxx A: xxxxxx xxxxxxxx I: xxxxxxxx T: xxx	S: xxxxxxxxxx E: xxxxxxxxxx O: xxxxxxx	U: xx F: xxxx R:xxxx

[1] Day is calculated as date – Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date – Date of first dose + 1 for dates on or after Baseline.
Note: Standardized Medication Name and ATC Level 2 Term map to the WHO-DDE (Version March 1, 2016).

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject Number, Start Date, End Date, Medication Name, Indication, and Route.

Listing 16.2.4.4.3: Prior and Concomitant Therapies and Procedures
Treatment Arm
(Page xx of yy)

Subject	Age/Sex Eval	C: System Organ Class P: Preferred Term M: Procedure/Therapy Name I: Indication	F: Date of First Application S: Start Date (Day)[1] E: End Date (Day)[1] O: Ongoing	T: BCC Treatment Y/N B: BCC Category I: BCC ID
xxxxxx	xxxx xx	C: xxxxxxxxxxxxx P: xxxxxx xxxxxxx M: xxxxxxxxxx I: xxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx O: xxxxxxxxxx xxxx	T: xxx B: xxxxxxxxx xxxxxxx xxxxx I: xxx

[1] Day is calculated as date – Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date – Date of first dose + 1 for dates on or after Baseline.
Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 19.0).

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject Number, Start Date, End Date, Procedure/Therapy Name, Indication, and Route.

Listing 16.2.4.5: Cleansers, Sunscreens and Moisturizers
Treatment Arm
(Page xx of yy)

Subject	Age/Sex Eval	P: Product Name T: Product Type F: Date of First Application	S: Start Date (Day)[1] E: End Date (Day)[1] O: Ongoing	F: Frequency
xxxxxx	xxxx xx	P: xxxxxxxxxxxxx T: xxxxxx xxxxxxx F: xxxxxxxxxx	S: xxxxxxxxxx E: xxxxxxxxxx xxxx O: xxxxxxxxxx xxxx	F: xxx

[1] Day is calculated as date - Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date - Date of first dose + 1 for dates on or after Baseline.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject Number, Start Date, End Date, Product Name, Type.

Listing 16.2.5.1: Study Medication Accountability Log
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Kit Number	Tube Number	Date Dispensed	Dispense Weight (gm)	Date Returned	Return Weight (gm)
xxxxx	xx/x	xxxxx	xxx	xxx	2016-07-26	xxx	2016-08-08	xx.x

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

If Not Done is checked for Dispensation / Weighed at Dispense / Returned then put NOT DONE for Date Dispense / Return,

Listing 16.2.5.2: Drug Exposure Information
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	F: Date of First Application L: Date of Last Application	F: Number of Doses on Date of First Application L: Number of Doses on Date of Last Application	D: Date of Missed Application(s) N: Number of Missed Application(s) R: Reason for Missed Application(s)
S: xxxxxx A: xxxx E: xxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	F: x L: xxxxxxx	D: xxxxxxxxxx N: xxxxxxx R: x xxxxxxxx xxxx x xxxxxx xxx xxx xxxxxxxxxxx xx xxxx xxxxxxxx xx xxxxxxxxxxx xxx xxx xxxxx xx
			D: xxxxxxxxxx N: x R: xxxx xxxxxxx
S: xxxxxx A: xxxx E: xxxx	F: xxxxxxxxxx L: xxxxxxxxxx	F: x L: x	
S: xxxxxx A: xxxx E: xxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	F: x L: x	
S: xxxxxx A: xxxx E: xxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	F: x L: xxxxxxx	D: xxxxxxxxxx N: x R: xxxxxxx xxxxxx
S: xxxxxx A: xxxx E: xxxx	F: xxxxxxxxxx L: xxxxxxxxxx	F: x L: x	

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing Format May Be Altered on Confirmation of Dosing Data Capture.

Listing 16.2.5.3: Drug Compliance
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Total Number of Applications	Expected Number of Applications	Compliance (%)
xxxxx	xx/x	xxxxx			

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.6.1: Assessment of Treatment Targeted Basal Cell Carcinomas
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex	Eval	Visit	Visit Date	BCC ID	Body Location	Greatest Diameter	Classification	Photographed	Biopsied	Excised	ISGTA
S: xxxxxx A: xxxx	xxxxxxxx	xxxxxx	xxxxxx	xx	xxxxxxxx	xx mm	xxxxxxxxxxx	X	X		xxxxx xxx
				xx	xxxxxxxx	xx mm	xxxxxxxxxxx	X	X		xxxxx xxx
		xxxxxx	xxxxxx	xx	xxxxxxxx	xx mm	xxxxxxxxxxx	X	X	X	xxxxx xxx
				xx	xxxxxxxx	xx mm	xxxxxxxxxxx	X	X	X	xxxxx xxx
S: xxxxxx A: xxxx	xxxxxxxx	xxxxxx	xxxxxx	xx	xxxxxxxx	xx mm	xxxxxxxxxxx	X	X		xxxxx xxx
				xx	xxxxxxxx	xx mm	xxxxxxxxxxx	X	X		xxxxx xxx
		xxxxxx	xxxxxx	xx	xxxxxxxx	xx mm	xxxxxxxxxxx	X	X	X	xxxxx xxx
				xx	xxxxxxxx	xx mm	xxxxxxxxxxx	X	X	X	xxxxx xxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Note to Programmer: Some fields apply only at certain visits (eg. Excised at Week 12 / ET). Leave blank at other visits.

Listing 16.2.6.2: GLI1 mRNA Levels
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	V: Visit D: Date	Tumor Site	T: Total # Cells A: Avg Dots/Cell QC: QC Pass/Fail	C0: % cells in Bin 0 C1: % cells in Bin 1 C2: % cells in Bin 2	C3: % cells in Bin 3 C4: % cells in Bin 4	H: Hs-GLI1 H-Score P: Percent Change from baseline
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxx D: xxxxxxxx	xxxx	T: xx A: xx QC: xxxx	C0: xx C1: xx C2: xx	C3: xx C4: xx	H: xx.xx P: --
		xxxxx	T: xx A: xx QC: xxxx	C0: xx C1: xx C2: xx	C3: xx C4: xx	H: xx.xx P: xx.xx
S: xxxxxx A: xxxx E: xxxxxxxx	V: xxxxxxxx D: xxxxxxxx	xxxx	T: xx A: xx QC: xxxx	C0: xx C1: xx C2: xx	C3: xx C4: xx	H: xx.xx P: --
		xxxxx	T: xx A: xx QC: xxxx	C0: xx C1: xx C2: xx	C3: xx C4: xx	H: xx.xx P: xx.xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject Number, Visit, Date, Category.

Listing 16.2.6.3: Residual Tumor
Treatment Arm
(Page 1 of xx)

Subject	Age/Sex	Eval	Visit	Visit Date	BCC ID Number	Surgical Report Available?	Evidence / Location Of Residual Tumor?

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

If Evidence is 'Y' then add '/ Location' (Tumor Marker Sample, Hohs Layer, Other). If 'Other' then add text in Brackets.

Listing 16.2.6.4: Photographic Tumor Review
Treatment Arm
(Page 1 of xx)

Subject	Age/Sex	Eval	BCC ID Number

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Columns will be added as per file received by sponsor.

Listing 16.2.7.1.1: Assessment of Treatment Targeted Basal Cell Carcinomas: Local Signs and Symptoms
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex	Eval	Visit	Visit Date	BCC ID	Pain / Burning	Pruritus	Erythema	Edema	Scabbing / Crusting
S: xxxxxx A: xxxx	xxxxxxxx	xxxxxx	xxxxxx	xx	xx	xx	xx	xx	xx
				xx	xx	xx	xx	xx	xx
		xxxxxx	xxxxxx	xx	xx	xx	xx	xx	xx
				xx	xx	xx	xx	xx	xx
S: xxxxxx A: xxxx	xxxxxxxx	xxxxxx	xxxxxx	xx	xx	xx	xx	xx	xx
				xx	xx	xx	xx	xx	xx
		xxxxxx	xxxxxx	xx	xx	xx	xx	xx	xx
				xx	xx	xx	xx	xx	xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.7.1.2: Systemic Symptoms
Treatment Arm
(Page 1 of xx)

Subject	Age/Sex	Eval	Visit	Visit Date	Systemic Symptom	Result
xxxxx	xx/X	ITT/S	Baseline	xxxx-xx-xx	Fatigue	Xxx
					Loss or Change in Taste	Xxx
					Nausea	Xxx
					Vomiting	Xxx
					Diarrhea	Xxx
					Muscle Spasms or Cramps	Xxx
					Changes of Quality or Quantity of Hair in Treated Areas	Xxx
					Change in Frequency of Shaving	Xxx
					Other: xxxxxxx	Xxx
			Week 2	xxxx-xx-xx	Fatigue	Xxx
					Loss or Change in Taste	Xxx
					Nausea	Xxx
					Vomiting	Xxx
					Diarrhea	Xxx
					Muscle Spasms or Cramps	Xxx
					Changes of Quality or Quantity of Hair in Treated Areas	Xxx
					Change in Frequency of Shaving	Xxx
					Other: xxxxxxx	Xxx
			Week x	xxxx-xx-xx	Fatigue	Xxx
					Loss or Change in Taste	Xxx
					Nausea	Xxx
					Vomiting	Xxx
					Diarrhea	Xxx
					Muscle Spasms or Cramps	Xxx
					Changes of Quality or Quantity of Hair in Treated Areas	Xxx
					Change in Frequency of Shaving	Xxx
					Other	Xxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

If Other is marked No show only Other if other is marked Yes, show Other with specification.

Listing 16.2.7.2.1: Unique Adverse Events Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Adverse Event
xxxxx xxxxx xxxxx	xxxxx xxxxx xxxxx	xxxxxxxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx
	xxxxx xxxxx xxxxx	xxxxxxxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx
	xxxxxxxxxx	xxxxx xxxxx xxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx

Note: System Organ Class and Preferred Term map to MedDRA dictionary (Version 19.0).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by MedDRA System Organ Class, Preferred Term, and Adverse Event.

Listing 16.2.7.2.2: Adverse Events
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	C: System Organ Class P: Preferred Term V: Verbatim T: In Treatment Area	F: Date of First Application S: Start Date (Day)[1] E: End Date (Day)[1]	S: Severity R: Relationship to Study Drug E: Serious O: Outcome	A: Action Taken
xxxxxx	xxxx	xxxxxxxx	S: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx V: xxxxxxxxxxxxxxx T: xx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	S: xxxx R: xxxxxxxxxx E: xx O: xxxxxxxxx	A: xxxxxxxxxxxx
			S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xx T: xx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	S: xxxx R: xxxxxxxxxx E: xxx O: xxxxxxxxx	A: xxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx T: xx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	S: xxxx R: xxxxxxxxxx E: xx O: xxxxxxxxx	A: xxxxxxxxxxxx

[1] Day is calculated as date - Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date - Date of first dose + 1 for dates on or after Baseline.
Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version 19.0).

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject Number, Start Date, End Date, and Adverse Event.
Note Action Taken will consist of a concatenation of Action Taken Regarding Study Drug, Action Taken Regarding Hospitalization, Action Taken Concomitant Medication, Action Taken Procedure/Therapy, Action Taken Other, and Specify

Listing 16.2.7.2.3: Treatment-Emergent Serious Adverse Events
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	C: System Organ Class P: Preferred Term V: Verbatim T: In Treatment Area	F: Date of First Application S: Start Date (Day)[1] E: End Date (Day)[1]	S: Severity R: Relationship to Study Drug E: Serious O: Outcome	A: Action Taken
xxxxxx	xxxx	xxxxxxxx	S: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx V: xxxxxxxxxxxxxxx T: xx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	S: xxxx R: xxxxxxxxxx E: xx O: xxxxxxxxx	A: xxxxxxxxxxxxx
			S: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx V: xx T: xx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	S: xxxx R: xxxxxxxxxx E: xxx O: xxxxxxxxx	A: xxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	S: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx V: xxxxxxxxxxxxxxx T: xx	F: xxxxxxxxxx S: xxxxxxxxxx xxxx E: xxxxxxxxxx xxxx	S: xxxx R: xxxxxxxxxx E: xx O: xxxxxxxxx	A: xxxxxxxxxxxxx

Note: System Organ Class and Preferred Term map to the MedDRA dictionary (Version xx.x).
[1] Day is calculated as date - Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date - Date of first dose + 1 for dates on or after Baseline.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)
Listing sorted by Subject Number, Start Date, End Date, and Adverse Event.
Note Action Taken will consist of a concatenation of Action Taken Regarding Study Drug, Action Taken Regarding Hospitalization, Action Taken Concomitant Medication, Action Taken Procedure/Therapy, Action Taken Other, and Specify

Listing 16.2.7.2.4: Subjects Who Prematurely Discontinued Study and/or Discontinued Study Drug Due to Adverse Events
Treatment Arm
(Page xx of yy)

	Discontinuation		Adverse Events	
S: Subject A: Age/Sex E: Eval	F: Date of First Application L: Date of Last Application	D: Date (Day)[1] R: Primary Reason	A: Verbatim S: Severity R: Relationship to Study Drug	S: Start Date (Day)[1] E: End Date (Day)[1]
S: xxxxxxxxxxxxxx A: xxxx E: xxxxxxxx	F: xxxxxxxxxxxxxx L: xxxxxxxxxxxxxx	D: xxxxxxxxxxxxxx R: xxxxxxxxxxxxxx	A: xxxxxxxxxxxxxx S: xxxxxxxxxx R: xxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx
S: xxxxxxxxxxxxxx A: xxxx E: xxxxxxxx	F: xxxxxxxxxxxxxx L: xxxxxxxxxxxxxx	D: xxxxxxxxxxxxxx R: xxxxxxxxxxxxxx	A: xxxxxxxxxxxxxx S: xxxxxxxxxx R: xxxxxxxxxx	S: xxxxxxxxxxxxxx E: xxxxxxxxxxxxxx

[1] Day is calculated as date - Date of first dose for dates prior to Baseline. Otherwise, day is calculated as date - Date of first dose + 1 for dates on or after Baseline.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject Number, Start Date, End Date, and Adverse Event.

Listing 16.2.8.1: Serum Pregnancy Test
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date	Was the Specimen Collected	Results
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xxx	xxxxxxxx
			xxxx x	xxxxxxxxxx	xx	
			xxxx xxxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.8.2.1: Chemistry Laboratory Results
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Test	Visit	Visit Date	Results	Units	Reference Range Low	Reference Range High	Reference Range Indicator	Clinically Significant
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxx	xxx	xxx	x	xx	xxxxxx	xxx
		xxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxx	xxx	xxx	x	xx	xxxxxx	xxx
		xxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing filtered on LBCAT = 'Chemistry' and sorted by Subject Number, Test, Visit Date.

Listing 16.2.8.2.2: Hematology Laboratory Results
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Test	Visit	Visit Date	Results	Units	Reference Range Low	Reference Range High	Reference Range Indicator	Clinically Significant
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxxxxxxx xxxxx xxxxxxx xxxxxx xxxxxx	xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx	xxx xxx xxx xxx xxx	xxx xxxxxx xxxxxx xxxxxx xxxxxx	x	xx	xxxxxx	xxx xx xx xx xx
	xxxxxxxxx	xxxxxxxxx xxxxx xxxxxxx xxxxxx xxxxxx	xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxxxx	xxx xxx xxx xxx xxx	xxx xxxxxx xxxxxx xxxxxx xxxxxx	x	xx	xxxxxx	xxx xx xx xx xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing filtered on LBCAT='Hematology' and sorted by Subject Number, Test, Visit Date.

Listing 16.2.8.2.3: Urinalysis Laboratory Results
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Test	Visit	Visit Date	Results	Units	Reference Range	Indicator	Clinically Significant
S: xxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxx	xxx	xxx	xx - xx	xx	xxxxxx
A: xxxx		xxxxx	xxxxxxxxxxxx	xxx	xxxxxx			xx
E: xxxxxxxx		xxxxxxx	xxxxxxxxxxxx	xxx	xxxxxx			xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx			xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx			xx
	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxx	xxx	xxx	x	xx xxxxxx	xxx
		xxxxx	xxxxxxxxxxxx	xxx	xxxxxx			xx
		xxxxxxx	xxxxxxxxxxxx	xxx	xxxxxx			xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx			xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx			xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing filtered on LBCAT='Urinalysis' and sorted by Subject Number, Test, Visit Date.

Listing 16.2.8.3.1: Abnormal Chemistry Results
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Test	Visit	Visit Date	Results	Units	Reference Range Low	Reference Range High	Reference Range Indicator	Clinically Significant
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxx	xxx	xxx	x	xx	xxxxxx	xxx
		xxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxx	xxx	xxx	x	xx	xxxxxx	xxx
		xxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing filtered on LBCAT='Chemistry' and sorted by Subject Number, Test, Visit Date.

Listing 16.2.8.3.2: Abnormal Hematology Results
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Test	Visit	Visit Date	Results	Units	Reference Range Low	Reference Range High	Reference Range Indicator	Clinically Significant
S: xxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxx	xxx	xxx	x	xx	xxxxxx	xxx
A: xxxx		xxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
E: xxxxxxxx		xxxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxx	xxx	xxx	x	xx	xxxxxx	xxx
		xxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx
		xxxxxx	xxxxxxxxxxxx	xxx	xxxxxx				xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing filtered on LBCAT='Hematology' and sorted by Subject Number, Test, Visit Date.

Listing 16.2.8.3.3: Abnormal Urinalysis Results
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	Test	Visit	Visit Date	Results	Units	Reference Range	Indicator	Clinically Significant
S: xxxxxx A: xxxx E: xxxxxxxx	xxxxxxxxx	xxxxxxxxx xxxxx xxxxxxx xxxxxx	xxxxxxxxxxxx xxxxxxxxxxxx xxxxxxxxxxxx xxxxxxxxxxxx	xxx xxx xxx xxx	xxx xxxxxx xxxxxx xxxxxx	xx - xx	xx	xxxxxx xx xx xx
	xxxxxxxxx	xxxxxxxxx xxxxx xxxxxxx xxxxxx xxxxxx	xxxxxxxxxxxx xxxxxxxxxxxx xxxxxxxxxxxx xxxxxxxxxxxx xxxxxxxxxxxx	xxx xxx xxx xxx xxx	xxx xxxxxx xxxxxx xxxxxx xxxxxx	x	xx xxxxxx	xxx xx xx xx xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing filtered on LBCAT=Urinalysis and sorted by Subject Number, Test, Visit Date.

Listing 16.2.8.4: Vital Signs
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date	Vital Sign	Result	Units
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	Diastolic Blood Pressure	xx	xxxx
					Systolic Blood Pressure	xx	xxxx
					Pulse	xx	xxxxxxxxx
					Respiration Rate	xx	xxxxxxxxxxx
					Oral Temperature	xxxx	xxxxxxxxxx
			xxxxxxxx	xxxxxxxxxx	Diastolic Blood Pressure	xx	xxxx
					Systolic Blood Pressure	xx	
					Pulse	xx	xxxxxxxxx
					Respiration Rate	xx	xxxxxxxxxxx
					Oral Temperature	xxxx	x
					Height	xx	xxxxxxxxxxx
					Weight	xxx	xxx
			xxxx xx	xxxxxxxxxx	Weight	xxx	xx
			xxxx xxxxxxxxx	xxxxxxxxxx	Diastolic Blood Pressure	xx	xxxx
					Systolic Blood Pressure	xx	xxxx
					Pulse	xx	xxxxxxxxx
					Respiration Rate	xx	xxxxxxxxxxx
					Oral Temperature	xxxx	xxxxxxxxxx
					Weight	xxx	xxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject Number, Visit, Date, Vital Sign.

Listing 16.2.8.5: Clinical Evaluation
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date	Was Clinical Evaluation Performed?	Is the Subject Experiencing Adequate Healing? / Specify if No
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx	xx / xxxxxxxxxxxxxxxxx xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)